

### REMARKS/ARGUMENTS

Claims 31-47 are active and find support in the original claims. Independent Claims 31 and 44 incorporate structural limitations of prior Claim 5. Accordingly, no new matter has been introduced.

#### Restriction/Election

The Applicants previously elected with traverse, **Group II**, claims 1-10, wherein Z is substituted phenyl; and the species **diabetic retinopathy** (for Claim 4) and the compound **N-{4-[2-(4-{[amino(imino)methyl]amino}phenyl)ethyl]-5-[4-(methylsulfonyl)benzyl]-1,3-thiazol-2-yl]acetamide** (for Claims 5-7). The Applicants understand that examination will be extended to additional species upon an indication of allowability for the generic claim as it reads on the elected species.

#### Rejection—Double Patenting

Claims 1 and 4-10 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over Claims 24, 26, 29, 30, 33, 37, 38 and 42 of U.S. Application No. 11/505,321. The Applicants respectfully request that this provisional double patenting rejection be held in abeyance pending the identification of otherwise allowable subject matter in the present application. Upon an indication of allowability for the pending claims, the Applicants understand that the provisional double patenting rejection will be withdrawn, provided the claims in the copending application have not been allowed, MPEP 804(I)(B).

Rejection—35 U.S.C. §112, first paragraph

Claims 1-9 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement. This rejection is moot in view of the cancellation of these claims. It would not apply to the new claims for the following reasons. The initial burden is on the Office to establish a reasonable basis to question the enablement provided for the claimed invention, *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993), MPEP 2164.04. Moreover, the burden is on the Patent Office to provide reasons based on scientific principles, to doubt the objective enablement of Applicant's claimed invention. Applicant's disclosure must be taken as in compliance with the enabling requirement under 35 USC 112, first paragraph, unless, there is reason to doubt the objective truth of the statements contained therein, *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). For the present claims, the Office has not set forth reasons based on scientific principles why it believes the invention not to be enabled. Nevertheless, to expedite prosecution, the Applicants now address the *In re Wands* factors.

Independent Claim 5 is limited a method that uses compounds having the structure depicted by formula (I) and which function as vascular adhesion protein-1 (VAP-1) inhibitors. Undue experimentation would not be required to identify compounds of formula (I) having this function because (1) the nature of the invention is not complex and involves the administration of a VAP-1 inhibitor to treat a vascular hyperpermeable disease. The function of the inhibitor is linked to the treatment of the particular disease state. (2) The breadth of the claims is directed to the administration of VAP-1 inhibitors identified by their structure. (3) The specification provides guidance as to different types of vascular hyperpermeable diseases (pages 10-11) and the mode of administration (pages 22-26) for compounds or salts of formula (I). (4) Working examples are provided and the Examiner has acknowledged that the claims as directed to Compounds A and B are enabled. (5) The relative level of skill in the art is high, generally Ph.D. or M.D. level. (6) The degree of

predictability is high in view of the conserved structure of compounds of formula (I) and in view of the disclosure and exemplification of methods of evaluating the functional activity of these compounds (see the Examples on pages 246-250 of the specification). Accordingly, the Applicants respectfully submit that this rejection would not apply to the invention as now claimed.

Rejection—35 U.S.C. §112, first paragraph

Claims 1-3 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement. The Applicants thank the Examiner for indicating enablement for claims directed to inhibitory activity in human and rat plasma as well as in the diabetic rat model for compounds A and B. The compounds recited in the present claims have the ability to inhibit VAP-1 and thus would be understood by those of skill in the art to be able to treat diseases that are mediated by VAP-1. Moreover, as explained above, the Office has not met its burden for asserting nonenablement and undue experimentation would not be required to make and use the invention. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. §102

Claims 1-4, and 1 and 4, respectively, were rejected under 35 U.S.C. 102(b) as being anticipated by Garpenstand et al., Diabet. Med. 16:514, or by Smith et al., WO 02/02541. These rejections are now moot.

Rejection—35 U.S.C. §102

Claims 1, 4 and 5-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al., U.S. Patent No. 7,125,901. This rejection is moot in view of the cancellation of

the prior claims. It would not apply to the new claims as they read on the elected species (treatment of diabetic retinopathy) because Inoue et al. is not prior art against the present claims directed to treatment of vascular hyperpermeable disease.

The present application claims priority to Provisional U.S. Patent Application 60/458,370, which was filed March 31, 2003. The claims in this provisional application disclose application of VAP-1 inhibitors for vascular hyperpermeable disease.

On the other hand, the priority document for Inoue et al., Provisional Application No. 60/442,509, filed January 27, 2003 merely describes macular edema as a subject for treatment using VAP-1 inhibitors. No disclosure of treatment of vascular hyperpermeability disease is found in this Inuoe priority document. Also, the other Inuoe priority document Provisional Application No. 60/458,369, filed March 31, 2003, contains no such disclosure. Accordingly, Inoue et al. is not prior art against the present claims which claim treatment of vascular hyperpermeability disease and this rejection may now be withdrawn.

Conclusion

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now ready for allowance. An early notification to this effect is earnestly requested.


Respectfully submitted,

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